

Amendment dated September 11, 2008

Reply to Office Action dated March 11, 2008, Advisory Action dated August 13, 2008

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior listings and versions thereof.

1-67. (Cancelled).

68. (Currently amended) A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a solubility of at the most 0.1 % w/v in 0.1 N hydrochloric acid at room temperature,

the composition being in the form of a particulate composition or being based on a particulate composition, wherein either the particles of the particulate composition used in the manufacture of the composition have a mean particle size of at the most 250 micrometers, or

at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve;

wherein the quick release pharmaceutical composition contains the active substance in contact with an alkaline substance; and

the composition, when tested in accordance with the dissolution method I defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

69. (Cancelled).

70. (Currently amended) A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a pK_a value of at the most 5.5,

the composition being in the form of a particulate composition or being based on a particulate composition, wherein

either the particles of the particulate composition used in the manufacture of the composition have a mean particle size of at the most 250 micrometers, or

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at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve;

wherein the quick release pharmaceutical composition contains the active substance in contact with an alkaline substance; and

the composition, when tested in accordance with the dissolution method I defined herein, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

71. (Previously presented) A composition according to claim 68 or 70, wherein the composition, when subjected to dissolution method I as defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 55% w/w of total amount of active substance present in the composition within the first 20 minutes of the test.

72. (Previously presented) A composition according to claim 68 or 70, wherein the solubility of the therapeutically and/or prophylactically active substance in 0.1 N hydrochloric acid at room temperature is at the most 0.05% w/v.

73-74. (Cancelled).

75. (Previously presented) A composition according to claim 68 or 70, further comprising at least one pharmaceutically acceptable excipient.

76. (Previously presented) A composition according to claim 75, wherein the at least one pharmaceutically acceptable excipient is selected from the group consisting of binders, disintegrants, fillers and diluents.

77. (Previously presented) A composition according to claim 76, wherein the composition comprises a filler having binding properties.

78. (Previously presented) A composition according to claim 77, wherein the filler having binding properties is selected from the group consisting of lactose, sugar derivatives, calcium carbonate (CaCO_3), tricalcium phosphate ($\text{Ca}_3(\text{PO}_4)_2$), calcium hydrogen phosphate (CaHPO_4) and/or mixtures thereof.

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79. (Previously presented) A composition according to claim 76, wherein the filler having binding properties is calcium hydrogen phosphate.

80. (Previously presented) A composition according to claim 76, wherein the filler having binding properties as raw material has a mean particle size of at the most 140 μm .

81. (Cancelled).

82. (Previously presented) A composition according to claim 108, wherein the alkaline substance is an antacid or an antacid-like substance selected from the group consisting of sodium hydrogen carbonate, magnesium carbonate, magnesium hydroxide and magnesium metasilicate aluminate or mixtures thereof.

83. (Currently amended) A composition according to claim 81 82, wherein the mean particle size of the antacid-like substance as raw material is at the most 297 250 μm .

84. (Cancelled).

85. (Previously presented) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is a non-steroid anti-inflammatory drug substance (NSAID substance).

86. (Previously presented) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is selected from the group consisting of lornoxicam, diclofenac, nimesulide, ibuprofen, piroxicam, piroxicam (betacyclodextrin), naproxen, ketoprofen, tenoxicam, aceclofenac, indometacin, nabumetone, acemetacin, morniflumate, meloxicam, flurbiprofen, tiaprofenic acid, proglumetacin, mefenamic acid, fenbufen, etodolac, tolfenamic acid, sulindac, phenylbutazone, fenoprofen, tolmetin, acetylsalicylic acid, dexibuprofen, paracetamol, and pharmaceutically acceptable salts, complexes and/or prodrugs thereof and mixtures thereof.

87. (Previously presented) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is lornoxicam or a pharmaceutically acceptable salt, complex or prodrug thereof.

88. (Previously presented) A composition according to claim 68 or 70, comprising a further active drug substance.

89. (Previously presented) A composition according to claim 88, wherein the further active drug substance is an antidepressant, an opioid, a prostaglandine analogue, a glucocorticosteroid, a cytostaticum, a H₂ receptor antagonist, a proton pump inhibitor and/or an antacidum.

90. (Previously presented) A composition according to claim 88, wherein the further active drug substance is misoprostol, methotrexate, cimetidine, ranitidine, pantoprazole, omeprazole, lansoprazole, paracetamol, penicillaminutese, sulfasalazine and/or auranofin.

91. (Previously presented) A composition according to claim 68 or 70, in unit dosage form, wherein the unit dosage of the composition comprises from 1 to 32 mg of the therapeutically and/or prophylactically active substance.

92. (Previously presented) A composition according to claim 68 or 70 in unit dosage form, wherein the unit dosage comprises from 1 mg to 1.6 g of the therapeutically and/or prophylactically active substance.

93. (Currently amended) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is lornoxicam and a unit dosage of the composition contains 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32 or 36 mg of lornoxicam.

94. (Previously presented) A composition according to claim 68 or 70, wherein the water content in the composition is at the most 5% w/w determined by the LOD (loss on drying) method described herein.

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95. (Previously presented) A composition according to claim 68 or 70, comprising sodium hydrogen carbonate.

96. (Previously presented) A composition according to claim 68 or 70, comprising calcium hydrogen phosphate.

97. (Withdrawn) A method for the preparation of a composition according to any one of claims 68 and 70, the method comprising the steps of

i) mixing the therapeutically and/or prophylactically active substance with a) an alkaline substance, and b) a filler having binding properties,

ii) contacting the thus obtained powder mixture with an aqueous medium to obtain a wet powder,

iii) drying the thus obtained wet powder at a temperature above room temperature until the water content in the powder is at the most 5% w/w determined as described herein, to obtain a first particulate mixture, and

iv) sieving the thus obtained first particulate mixture.

98. (Withdrawn) A method according to claim 97, wherein the alkaline substance employed in step i) is an antacid-like substance.

99. (Withdrawn) A method according to claim 97, wherein the filler having binding properties is selected from the group consisting of lactose, sugar derivatives, calcium carbonate (CaCO_3), tricalcium phosphate, calcium hydrogen phosphate (CaHPO_4), and mixtures thereof.

100. (Withdrawn) A method according to claim 97, wherein the aqueous medium employed in step ii) is a solvent comprising water and an organic solvent.

101. (Withdrawn) A method according to claim 100, wherein the organic solvent is a solvent which is miscible with water.

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102. (Withdrawn) A method according to claim 100, wherein the concentration of the organic solvent in the solvent is from 0% v/v to 95% v/v.

103. (Withdrawn) A method according to claim 97, wherein the mean particle size of the particles of the first particulate mixture is at the most 100% larger than the mean particle size of the powder mixture from step i) before subjecting the powder mixture to the reaction in the aqueous medium employed in step ii).

104. (Withdrawn) A method according to claim 97, wherein the mean particle size of the particle of the first particulate mixture is at the most 90% larger than the mean particle size of the powder mixture from step i) before subjecting the powder mixture to the reaction in an aqueous medium employed in step ii).

105. (Withdrawn) A method according to claim 97, wherein the powder obtained in step i) has such a particle size that when the powder is subjected to a sieve analysis, at least 90% w/w of the particles pass through sieve 180 μm , and the first particulate mixture obtained in step iii) has such a particle size that when the particulate composition is subjected to a sieve analysis, at least 50% w/w of the particles passes through sieve 180 μm .

106. (Withdrawn) A method according to claim 97, wherein the mean particle size of the particles of the first particulate mixture is at the most 250 μm .

107. (Withdrawn) A method for treatment and/or prophylaxis of acute pain and/or mild or moderate pain comprising administering to a patient an effective amount of a therapeutically and/or prophylactically active substance in the form a quick release composition according to any one of claims 68 and 70.

108. (Currently amended) A composition according to claim 81 82, wherein the alkaline substance is an antacid or an antacid-like substance.

109. (Previously presented) A composition of claim 68 or 70, wherein when tested according to the dissolution method I defined herein employing 0.07 N hydrochloric acid

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as dissolution medium, releases at least 80% w/w of the active substance within the first 20 minutes of the test.

110. (Cancelled).

111. (Previously presented) A composition of claim 68 or 70, wherein the quick release pharmaceutical composition is a coated tablet.

112. (Withdrawn) The method of claim 97, further comprising adding a further pharmaceutically acceptable excipient to obtain a second particulate mixture.

113. (Withdrawn) The method of claim 97, further comprising compressing the thus obtained second particulate mixture into tablets.

114. (Withdrawn) The method of claim 113, further comprising coating the tablets.

115. (New) The composition of claim 68, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, water, ethanol, and calcium stearate.

116. (New) The composition of claim 68, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, and calcium stearate.

117. (New) The composition of claim 70, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, water, ethanol, and calcium stearate.

118. (New) The composition of claim 70, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, and calcium stearate.

119. (New) The composition of claim 68, wherein the composition has a mechanical strength to enable the composition to be coated using traditional coating equipment.

120. (New) The composition of claim 70, wherein the composition has a mechanical strength to enable the composition to be coated using traditional coating equipment.

121. (New) The composition of claim 68, further comprising a filler having binding properties, wherein the composition comprising the binder in the form of tablets having a diameter of 9.5 mm when subjected to a crushing strength test in accordance with Ph. Eur. has a crushing strength of at least about 50N.

122. (New) The composition of claim 70, further comprising a filler having binding properties, wherein the composition comprising the binder in the form of tablets having a diameter of 9.5 mm when subjected to a crushing strength test in accordance with Ph. Eur. has a crushing strength of at least about 50N.